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(54) METHOD AND APPARATUS FOR VASCULAR DURABILITY AND FATIGUE TESTING

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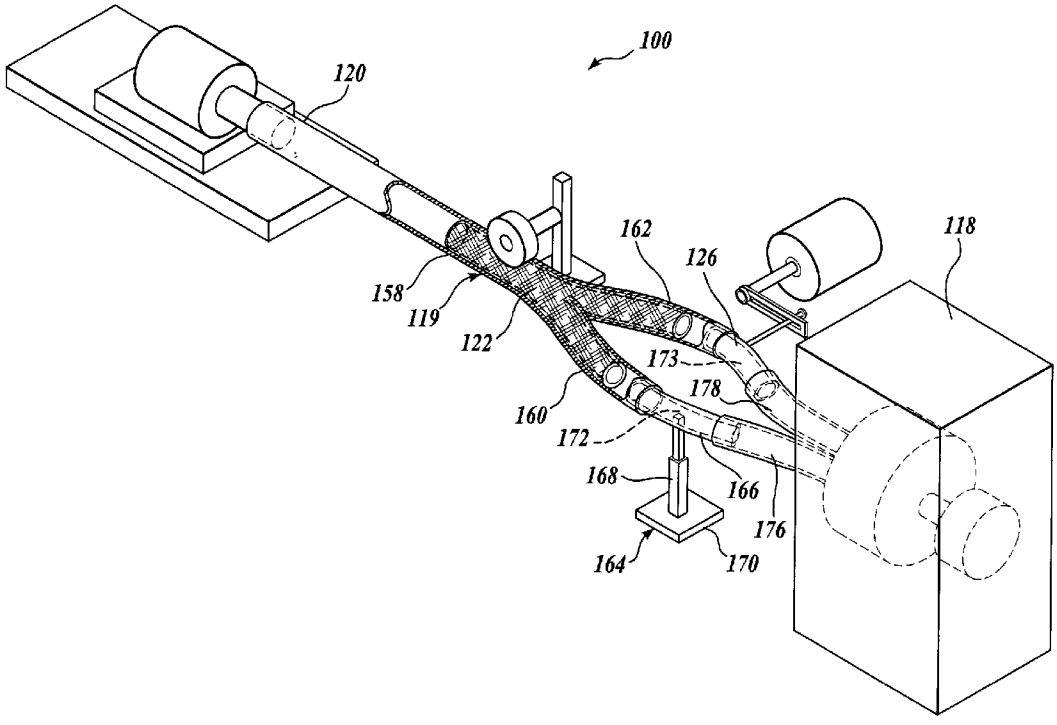
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(57) **ABSTRACT**

A vascular prosthesis tester (**10**) for inducing stresses upon a vascular prosthesis (**22**) having a channel extending through the vascular prosthesis is disclosed. The tester includes a pump (**18**) adaptable to pressurize a fluid disposed within the channel to induce a radial stress upon the vascular prosthesis. The tester may further include a bend applicator (**16**) operable to induce a bending stress, a torque applicator (**12**) operable to induce a torque, a linear force applicator (**52**) operable to induce a linear force, and/or a stop (**28**) for inducing a lateral push stress upon the vascular prosthesis. A method of fatigue testing a vascular prosthesis contained within a fluid conduit is also disclosed. The method includes injecting a fluid within the inner channel and inducing a torque, bending stress, linear stress, and/or later push stress upon the vascular prosthesis.



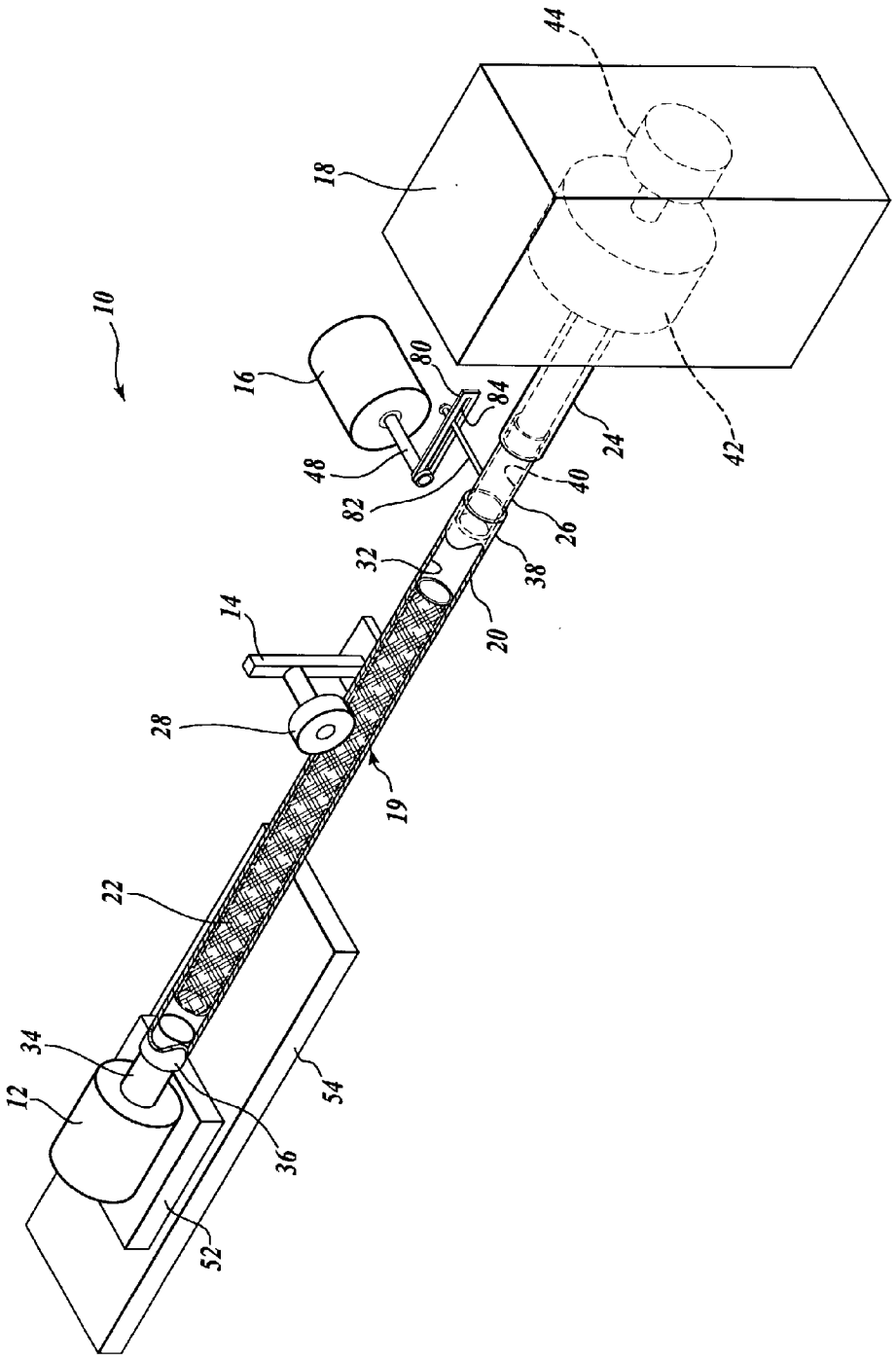


Fig. 1.

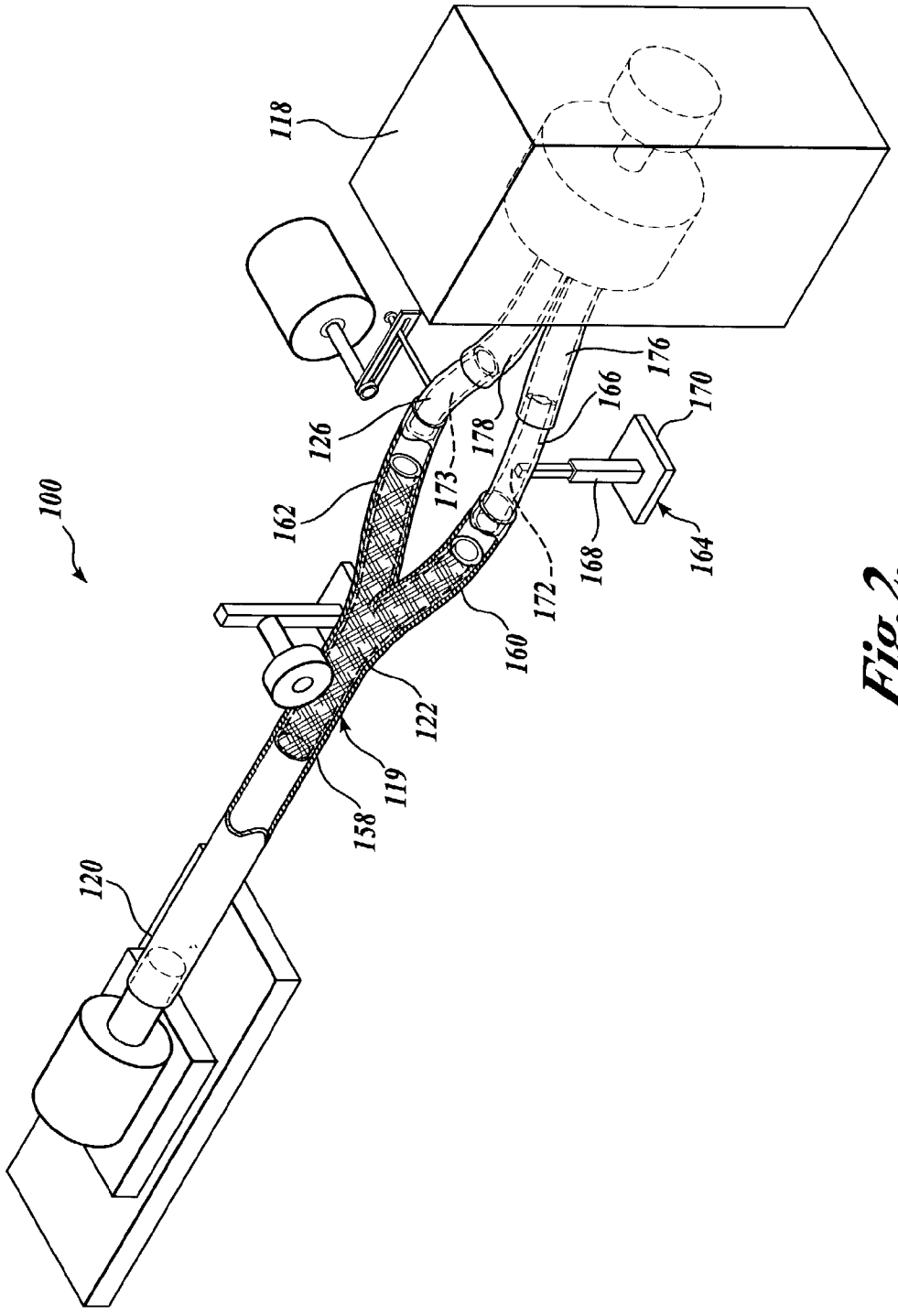

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Fig. 2.

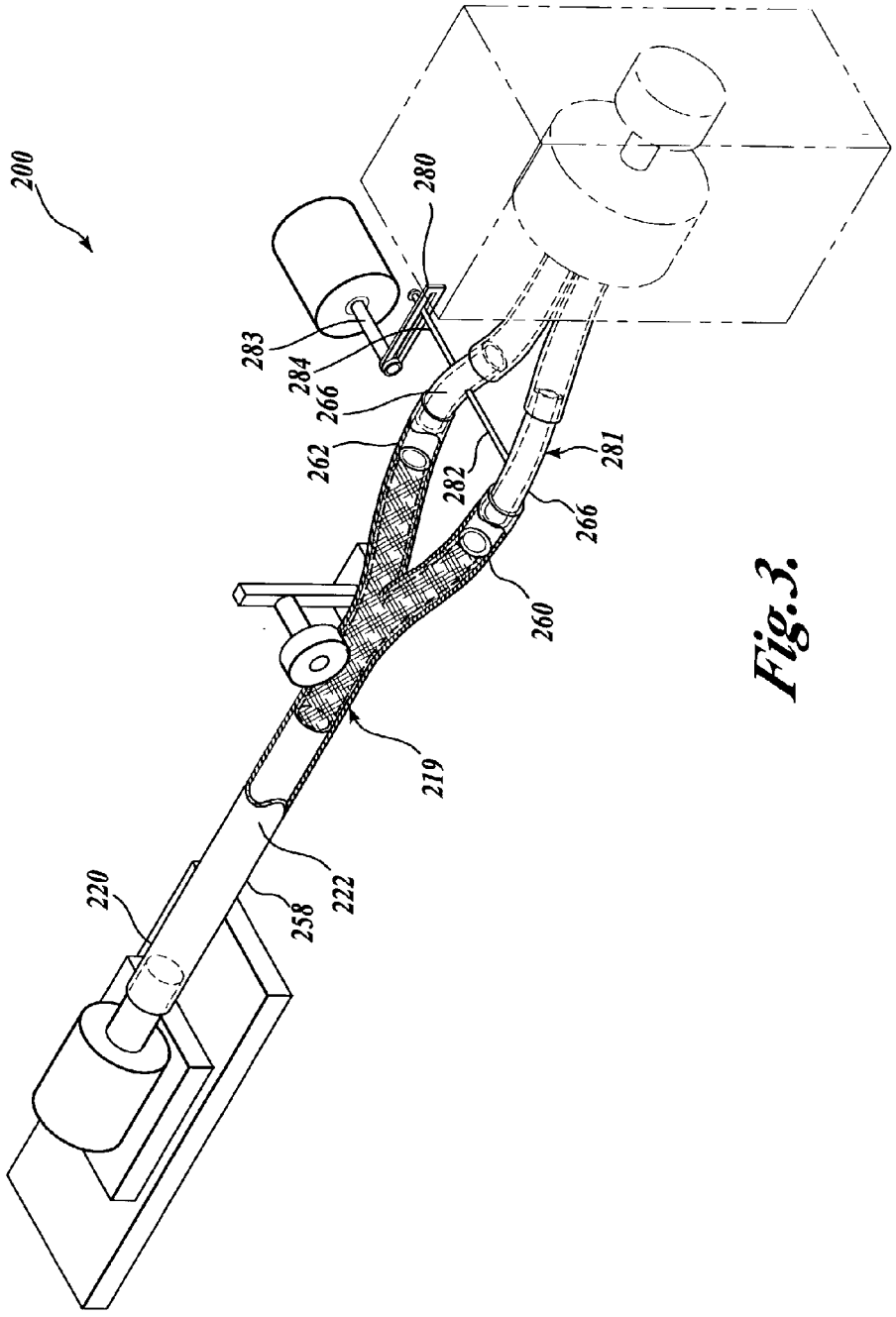


Fig. 3.

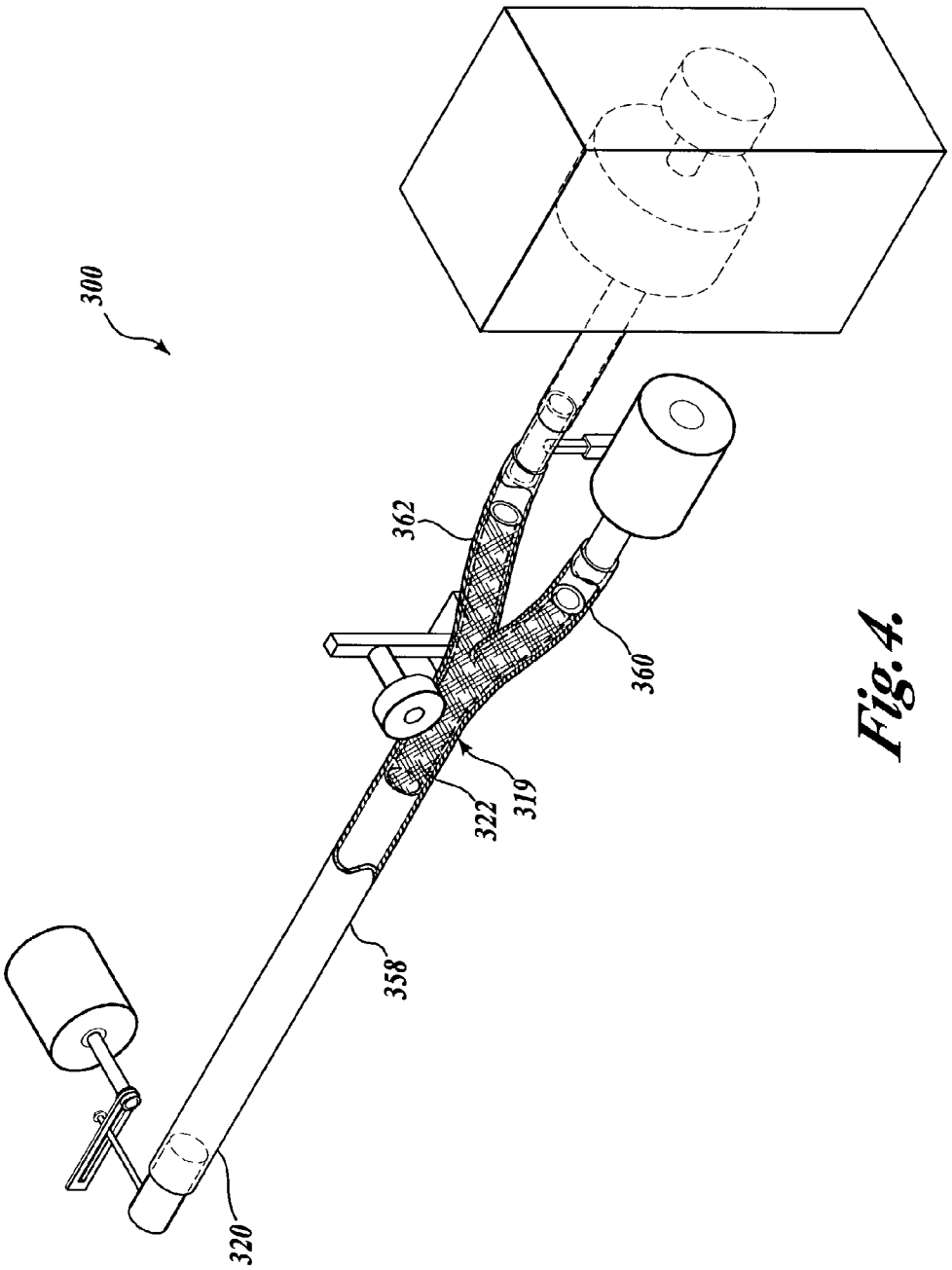


Fig. 4.

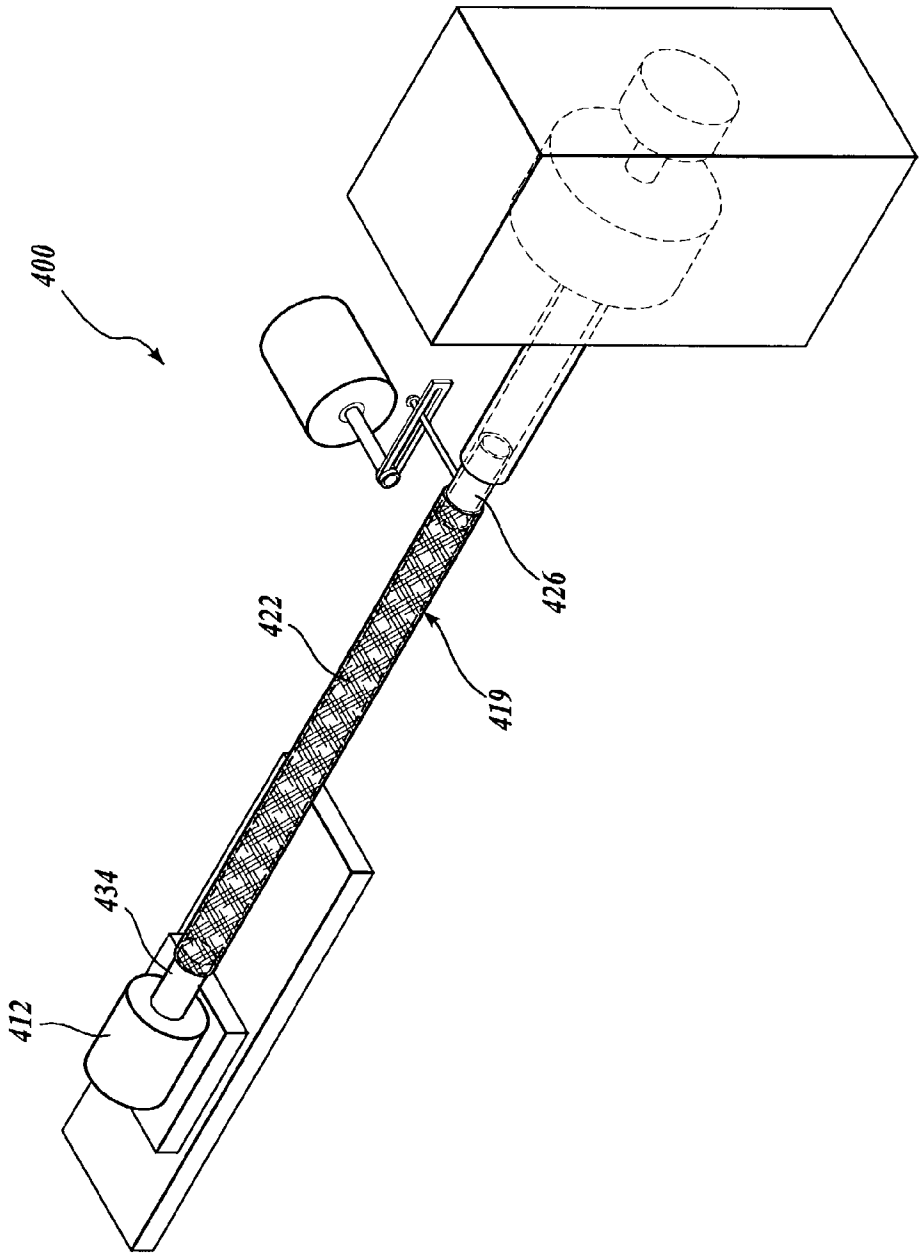


Fig. 5.

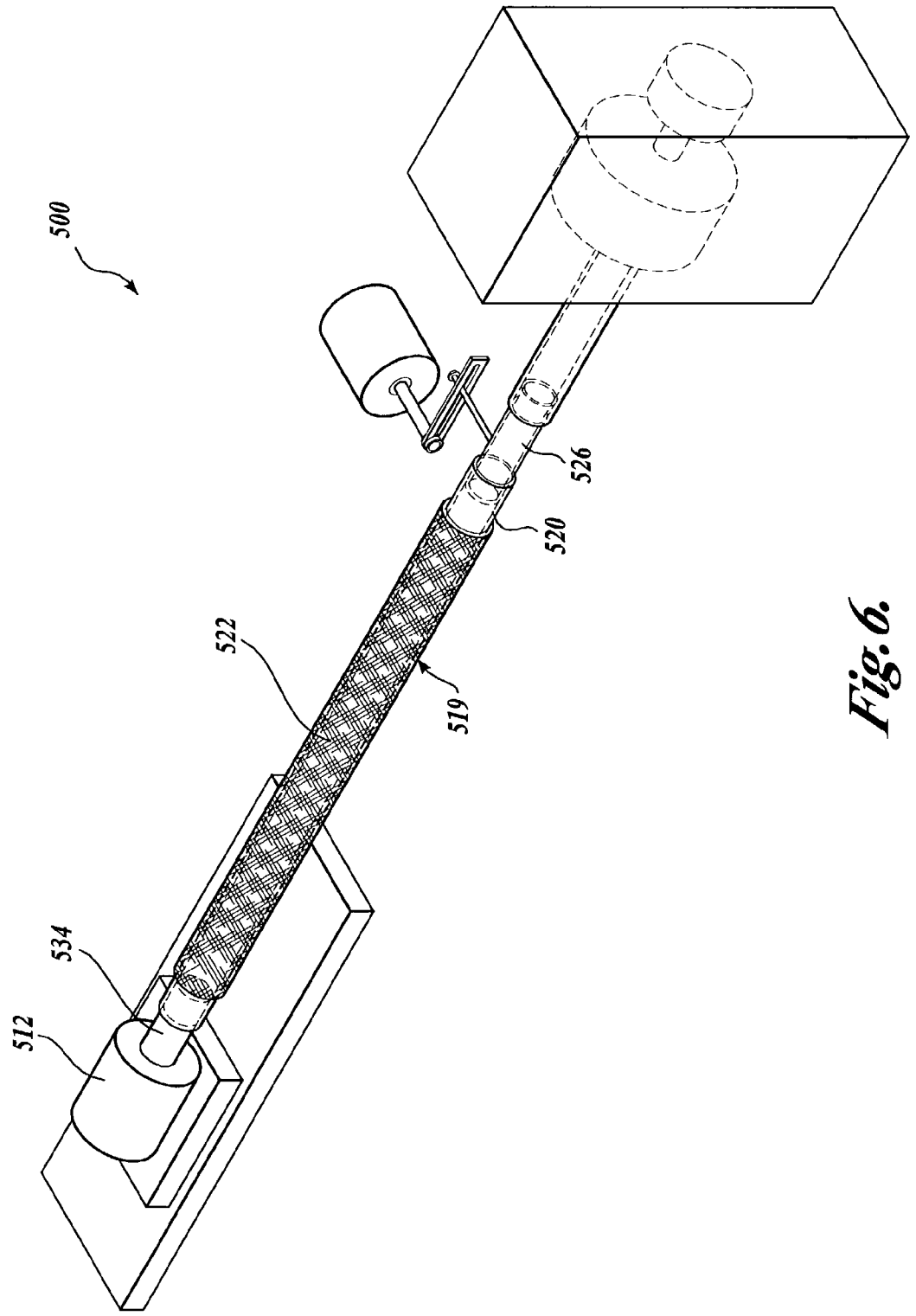


Fig. 6.

METHOD AND APPARATUS FOR VASCULAR DURABILITY AND FATIGUE TESTING

FIELD OF THE INVENTION

[0001] The present invention relates generally to the field of vascular prosthesis testing, and more particularly, to vascular prosthesis testing that simulates physiological loading conditions.

BACKGROUND OF THE INVENTION

[0002] Vascular prosthesis, such as stents, grafts, and stent-grafts are often used in the medical field to repair vascular abnormalities in a patient. In one such non-limiting example, a vascular prosthesis may be used to repair an Abdominal Aortic Aneurysm (hereinafter "AAA"). An AAA is an abnormal dilation of the abdominal part of the aorta, which is frequently fatal if ruptured. Conventional surgical repair requires a major operation. An alternative treatment strategy is known as vascular stent grafting. In vascular stent grafting, a stent-graft is positioned within the dilated portion of the aorta to reduce the pressure in the aneurysm sac. The stent-graft is a combination of a structural metal skeleton stent and an outer polyester fabric graft. The stent-graft is delivered through a catheter and is positioned using X-ray guidance and interventional radiological techniques. The successful completion of the procedure means that the aneurysm is excluded from circulation, blood is not leaked to the aneurysm, and that the stent-graft does not block any vital branch arteries.

[0003] Inasmuch as the stent-graft is placed within the aorta of the patient, the stent-graft is subjected to physiological loading conditions for the life of the stent-graft or the patient. Therefore, it is apparent that sufficient testing of the stent-graft's fatigue and durability characteristics is important. When stent-grafts were developed to treat AAA, the pre-clinical testing required involved mainly extensions of the tests required for stents intended to treat stenotic disease to AAA stent-grafts. Stents for stenotic disease are typically required to withstand only external radial compression, and the prior art fatigue tests reflect this singular requirement. The prior art devices utilized for testing stent fatigue failure feature simple straight compliant tubes in which the pressure is cycled over time to model the stresses induced by the pumping of the heart.

[0004] A testing regime limited to fluid-pressure-induced stresses fails to adequately simulate the physiological stresses exhibited upon a stent-graft, since the physiological stresses exhibited upon an AAA stent-graft are substantially more complex and varied than a stenotic stent. For example, stenotic stents are deployed over relatively short lengths of a vessel, such as a few centimeters, where the vessel remains relatively stationary. In contrast, AAA stent-grafts having lengths of 30 to 40 centimeters are deployed into vessels that feature curvatures and branches. Furthermore, the geometric features of the vessels change significantly during normal physiologic movements, such as sitting or walking, thereby subjecting the stent-graft to varying dynamic mechanical stress. Also, the stent-grafts may be subjected to more gradually varying mechanical stresses, such as would occur as gradual changes in the aneurysm morphology occur, such as the shrinkage of the aneurysm.

[0005] Therefore, there exists a need for a vascular prosthesis-testing device that more fully simulates the varied physiological stresses induced upon an AAA stent-graft when present in the human body. More specifically, there exists a need for a vascular prosthesis testing device that is operable to induce, in addition to internal fluid pressure stresses, linear compressive, linear tension, torsion, lateral push, and bending stresses, in an oscillatory and/or variable manner, upon a vascular prosthesis.

SUMMARY OF THE INVENTION

[0006] In accordance with the present invention, a vascular prosthesis tester for inducing mechanical stresses upon a vascular prosthesis having a channel extending along a longitudinal axis is provided. The vascular prosthesis tester includes a pump adaptable to pressurize a fluid disposed within the channel of the vascular prosthesis to induce a radial strain upon the vascular prosthesis. The tester may further include a bend applicator operable to induce a bending stress upon the vascular prosthesis by bending the vascular prosthesis substantially along the longitudinal axis. The tester may further include a torque applicator operable to induce a torque oriented substantially about the longitudinal axis upon the fluid conduit. The tester may also include a linear force applicator operable to induce a linear force oriented substantially parallel with the longitudinal axis upon the vascular prosthesis.

[0007] In accordance with further aspects of the present invention, the vascular prosthesis tester may further include a stop. The stop is operable to engage the fluid conduit and limit the perpendicular displacement of the fluid conduit in at least one direction when the fluid conduit is coupled to the vascular prosthesis tester. In accordance with additional aspects of the present invention, the pump, bend applicator, torque applicator, linear force applicator, and/or stop are operable to induce an oscillatory or gradually varying force or pressure within the channel.

[0008] In accordance with the present invention, a method of fatigue testing a vascular prosthesis having an inner channel oriented along a longitudinal axis of the vascular prosthesis is provided. The steps of the method include injecting a pressurized fluid within the inner channel to induce a radial stress upon the vascular prosthesis and inducing a torque, bending stress, and/or linear stress upon the fluid conduit. The torque may be induced substantially about the longitudinal axis. The bending stress may be induced substantially along the longitudinal axis. The linear stress may be induced substantially parallel with the longitudinal axis.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same become better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

[0010] **FIG. 1** is a perspective view of one embodiment of a vascular prosthesis tester formed in accordance with the present invention with a portion of a fluid conduit cut-away to reveal a stent-graft contained within the fluid conduit, the fluid conduit shown in relation to a plurality of force applicators;

[0011] **FIG. 2** is a perspective view of a first alternate embodiment of a vascular prosthesis tester formed in accor-

dance with the present invention with a portion of a bifurcated fluid conduit cut-away to reveal a bifurcated stent-graft contained within the bifurcated fluid conduit, the bifurcated fluid conduit shown in relation to a plurality of force applicators;

[0012] **FIG. 3** is a perspective view of a second alternate embodiment of a vascular prosthesis tester formed in accordance with a portion of a bifurcated fluid conduit cut-away to reveal a bifurcated stent-graft contained within the bifurcated fluid conduit, the bifurcated fluid conduit shown in relation to a plurality of force applicators;

[0013] **FIG. 4** is a perspective view of a third alternate embodiment of a vascular prosthesis tester formed in accordance with a portion of a bifurcated fluid conduit cut-away to reveal a bifurcated stent-graft contained within the bifurcated fluid conduit, the bifurcated fluid conduit shown in relation to a plurality of force applicators;

[0014] **FIG. 5** is a perspective view of a fourth alternate embodiment of a vascular prosthesis tester formed in accordance with the present invention with a stent-graft depicted in relation to a plurality of force applicators; and

[0015] **FIG. 6** is a perspective view of a fifth alternate embodiment of a vascular prosthesis tester formed in accordance with the present invention with a stent-graft depicted on the outer surface of a fluid conduit shown in relation to a plurality of force applicators.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0016] **FIG. 1** illustrates a vascular prosthesis tester **10** formed in accordance with one embodiment of the present invention and suitably used for inducing mechanical stresses upon a vascular prosthesis, such as a stent-graft **22**. The illustrated embodiment of the vascular prosthesis tester **10** of the present invention is configured to subject a stent-graft **22** to tensile and/or compressive axial loads, bending stresses, torsional stresses, lateral push stresses, pressure-induced radial strain, and/or fluid shear stresses. The forces may be applied in an oscillatory or gradually varying manner by force applicators or actuators, which may be driven by mechanical, electrical, pneumatic, hydraulic or other suitable means. Further, the actuators may induce the stresses independently or in combination, or in a manner to simulate a physiologic movement, such as walking.

[0017] The forces are applied upon what, for the purposes of this detailed description, will be generally referred to as a test member. The test member is comprised of a stent-graft **22** and an optional fluid conduit **22**, both of which will be described in further detail below. More specifically, the test member may be comprised of stent-graft **22** only, as shown in **FIG. 5, a** stent-graft **22** disposed on the outer surface of the fluid conduit **20**, as shown in **FIG. 6**, and the stent-graft **22** contained within a channel of the fluid conduit **20**, as shown in FIGS. **1-4**.

[0018] Although the illustrated embodiment of the present invention is described as operable for testing stent-grafts for illustrative purposes, one skilled in the relevant art will appreciate that the disclosed vascular prosthesis tester **10** is suitable for testing other types of vascular prosthesis, such as stents and grafts, for example. Therefore, it should be apparent to one skilled in the art that the vascular prosthesis tester **10** has wide application, and may be used in any situation where subjecting a vascular prosthesis to realistic physiologic mechanical stresses is desirable.

[0019] Focusing now on the physical components of the invention, the vascular prosthesis tester **10** includes a torque inducing rotary motor **12**, a linear motor **52**, a bend-inducing rotary motor **16**, a diaphragm pump **18**, and a roller **28**. The vascular prosthesis tester **10** further includes a test member **19** comprised of a fluid conduit **20** manufactured to recreate the physical properties and characteristics of a vessel intended to receive the stent-graft **22**, and a stent-graft **22**.

[0020] Focusing now more fully on the fluid conduit **20**, the fluid conduit **20** is formed with a longitudinally aligned inner channel **32** for receiving the stent-graft **22** therewithin. In one embodiment of the present invention, the fluid conduit **20** is made of a transparent silicone elastomer. The fluid conduit **20** may be a single straight fluid conduit as shown or a bifurcated or branched fluid conduit such as shown in **FIG. 2**, selected to correspond with the size and shape of a human aorta. The fluid conduit **20** may be made by casting the material between an inner mandrel made of a polished metal rod, and a removable outer shell in a manner to exhibit compliance representative of a physiological counterpart. Or the fluid conduit **20** may be formed by applying a selected liquid material to a rotating mandrel. Such a method of formation for forming a fluid conduit suitable for use with the present invention is disclosed in Moore et al., *A Device for Subjecting Vascular Endothelial Cells to Both Fluid Shear Stress and Circumferential Cyclic Stretch, Annals of Biomedical Engineering*, Vol. 22, pp. 416-422 (1994).

[0021] More specifically, the Moore et al article discloses forming a fluid conduit suitable for use in the present invention by applying a very thin layer (~0.2 mm) of a silicone elastomer, such as the silicone elastomer sold under the trademark SYLGARD® 184 by DOW CORNING®, in a liquid state to a highly polished6 mm diameter cylinder that is constantly and slowly rotated in an oven at 150° C. The application of liquid silicone elastomer to the mandrel is carefully controlled to ensure that the thickness of the fluid conduit does not vary around the circumference or along the length. The fluid conduit is then allowed to solidify inside the oven, and then is carefully removed from the mandrel.

[0022] The inner surface of the fluid conduit **20** may be lined with a grid pattern so that any deformation of the stent-graft **22** occurring during testing may be measured optically. The grid may be produced by machining shallow, narrow grooves in the outer surface of the mandrel. The narrow groves may be filled with black powder, such as printer toner, to provide visual indicia to facilitate optical deformation measuring.

[0023] Once the fluid conduit **20** is formed, a stent-graft is placed within the inner channel **32** for testing. The inner diameter of the inner channel **32** is selected to provide a friction fit of the stent-graft **22** within the inner channel **32**, so that any force applied to the fluid conduit **20** is also exhibited upon the stent-graft **22**. After insertion of the stent-graft **22** within the fluid conduit **20**, a first end **36** of the fluid conduit **20** may be rigidly coupled to an axial aligned drive shaft **34** of a rotary motor **12**. In one actual embodiment of the present invention, the rotary motor **16** is a four-phase hybrid 1.8-degree step motor, model number

42D225, manufactured by Anaheim Automation, located at 910 East Orangefair Lane, Anaheim, Calif., 92801-1195.

[0024] The rotary motor **12** may be computer controlled to induce a torsional stress upon the fluid conduit **20**, and thus the stent-graft **22** contained therewithin, by rotation of the drive shaft **34** and thus the attached first end **36** of the fluid conduit **20**. The rotary motor **12** may be controlled by computer to apply the torsional stress in an oscillatory manner, having a frequency and amplitude selected by the user. As a non-limiting example, the oscillatory stress may be applied by rotating the first end **36** of the fluid conduit **20** from a neutral position clockwise to a selected angular displacement. The rotary motor **12** may then rotate the first end **36** of the fluid conduit **20** back to the neutral position, or alternatively, rotate the first end **36** to a selected angular displacement in a counterclockwise direction. As should be apparent to one skilled in the art, the cycle may be repeated and varied as desired.

[0025] The rotary motor **12** may also apply the torsional stress in a substantially variable manner, where the first end **36** of the fluid conduit **20** is rotated and held at a selected angular displacement. It will be appreciated by one skilled in the art, that the term "variable" and the phrase "gradually varying" used within this detailed description include embodiments where a force is applied and held at a relatively constant level as described above, but also includes embodiments where the force is gradually increased or decreased over a selected time period, the time period being substantially greater than the frequency of oscillatory applied forces.

[0026] The vascular prosthesis tester **10** is also capable of inducing linear compressive and tensile stresses upon the fluid conduit **20** and the stent-graft **22**. To accomplish this, a linear motor **52** selectively adjusts the longitudinal position of a rigidly attached rotary motor **12**, thereby selectively applying linear forces upon the fluid conduit **20**. More specifically, the linear motor **52** is a single-axis linear stepper motor that reciprocates in a longitudinal manner along the length of a stationary platen **54** in a direction substantially parallel to the length of the fluid conduit **20**. The linear motor **52** is computer controlled to selectively reciprocate along the stationary platen **54**, thereby adjusting the linear position of the attached rotary motor **12** to selectively induce linear stresses (either tensile or compressive) upon the fluid conduit **20** and the stent-graft **22** contained therewithin.

[0027] The linear stresses may be applied in an oscillatory manner having a frequency and amplitude selected by the user. As a non-limiting example, the oscillatory stress may be applied by extending the linear motor **52** toward the first end **36** of the fluid conduit **20** from a neutral position to a selected extended position, thereby applying compressive forces upon the fluid conduit **20**. The linear motor **52** may then retract along the stationary platen **54** back to the neutral position, or alternatively, continue retracting to a selected retracted position, thereby applying a tensile stress upon the fluid conduit **20**. The described cycle may be repeated and varied as desired. The linear motor **52** may also apply the stress in a variable manner, where the fluid conduit **20** is induced with a constant (or gradually increasing or decreasing) linear stress. In one embodiment of the present invention, the linear motor **52** is a single-axis linear stepper motor, model number LMSS-1304-2WW1, manufactured by Baldor Electric Company, located at 5711 R. S. Boreham, Jr. St., P.O. Box 2400, Fort Smith, Ariz., 72901.

[0028] The vascular prosthesis tester **10** is also operable to apply radial and fluid shear stresses upon a stent-graft. To accomplish this, a second end **38** of the fluid conduit **20** is coupled in fluid communication with the diaphragm pump **18** by a section of flexible tubing **24**. The diaphragm pump **18** is controlled to generate a cyclic or oscillating pressure gradient in a fluid, such as a saline solution, contained within the fluid conduit **20** and flexible tubing **24**. The oscillating pressure gradient is preferably selected to model the physiologic pressure gradients induced in the arteries of a human by the beating of the heart. A fitting **26**, having an inner passageway **40**, is used to couple the flexible tubing **24** of the diaphragm pump **18** in fluid communication with the second end **38** of the fluid conduit **20**.

[0029] Focusing now on the pump **18**, the pump **18** includes a diaphragm **42** having the saline solution disposed on a first side of the diaphragm **42**, and a driver **44** for driving the diaphragm **42** in a reciprocating manner on a second side of the diaphragm **42**. The driver **44** may be reciprocatingly driven by any means known in the art, such as by a linear voice-coil motor **44** as disclosed in U.S. Pat. No. 5,670,708, issued to Vilendrer, the disclosure of which is hereby expressly incorporated by reference. Or alternately, the diaphragm may be mechanically driven, such as by a rotary motor coupled to a rotary to linear conversion component, such as disclosed in U.S. Pat. No. 4,972,721, issued to Conti, the disclosure of which is hereby expressly incorporated by reference.

[0030] As the driver **44** reciprocatingly drives the diaphragm **42**, saline solution under pressure is injected within the fluid conduit **20**, selectively pressurizing the fluid conduit **20**. The selective pressurization and depressurization of the fluid conduit **20** induces circumferential (radial) hoop stresses and fluid shear stresses within the fluid conduit **20** and the stent-graft **22** contained therewithin. Although the pump **18** may apply pressure to the fluid conduit **20** in a variable manner, the pump **18** preferably drives the fluid in an oscillatory manner to model the stress applied by a change of blood pressure in a vessel during the pumping of the heart. Therefore, in one embodiment, the diaphragm is configured to provide fluid pressures in the range of 80 to 140 mm of mercury, analogous to the pressures produced by the pumping of the human heart. Further, although the frequency range of biological importance basically lies between 50 and 200 cycles per minute for the human heart, the frequency of the oscillatory application of the pressure gradient in the fluid conduit may be substantially increased above this range to 6,000 cycles per minute or higher to model the forces exerted upon a vascular prosthesis in a shortened period in the lab.

[0031] To determine the quantity of days simulated during a period of testing in the lab for a given pump pressure frequency and modeled heart rate, the following formula is used:

$$\text{days simulated} = \text{days tested in lab} \frac{\text{pump pressure frequency}}{\text{normal heart rate}}$$

[0032] For example, the stresses induced upon a stent-graft exhibited to an average of 100 beats per minute over a 60 day period may be simulated in one day in the lab when the diaphragm pump is operated at a frequency of 6,000 fluctuations per minute.

[0033] The vascular prosthesis tester **10** is also operable to apply bending stresses upon the fluid conduit **20**. To accomplish this, the fitting **26** described above for the pump **18** is coupled to the perpendicularly aligned rotary motor **16**. The fitting **26** is coupled to the rotary motor **16** via a slotted lever **80** and a torque shaft **82**. The slotted lever **80** is an elongate flat bar having a slot **84** longitudinally disposed along the length of the lever **80**. The slot **84** is sized to slidingly accommodate the torque shaft **82** therethrough. The torque shaft **82** is coupled to the fitting **26** in a pivotal or rigid manner, depending upon the type of bending stresses desired to be induced upon the fluid conduit **20** and stent-graft **22** contained therewithin.

[0034] The rotary motor **16** is computer controlled to rotate, thereby exhibiting the attached fluid conduit **20** and the stent-graft **22** contained within to bending stresses. The rotary motor **16** may be controlled by computer to apply the bending stress in a cyclic or oscillatory manner as selected by the user. As a non-limiting example, the oscillatory bending stresses may be applied by rotating the second end **38** of the fluid conduit **20** from a neutral position clockwise to a selected angular displacement, then rotating back to the neutral position, or alternatively, rotating the second end **38** to a selected angular displacement in a counterclockwise direction. The rotary motor **16** may also apply the bending stress in a variable manner, where the second end **38** is rotated and held at a selected angular displacement, or alternately, the angular displacement gradually increased or decreased. In one embodiment of the present invention, the rotary motor **16** is a four-phase hybrid 1.8-degree step motor, model number 42D225, manufactured by Anaheim Automation, located at 910 East Orangefair Lane, Anaheim, Calif., 92801-1195.

[0035] The vascular prosthesis tester **10** is also operable to apply lateral push stresses upon the fluid conduit **20**. To accomplish this, a stop in the form of a roller **28** is used in combination with the rotary motor **16**. The roller **28** engages the fluid conduit **20**, thereby limiting the perpendicular movement of the fluid conduit **20** in a radial direction. As is apparent to one skilled in the art, the roller **28** serves to manipulate the bending forces applied to the fluid conduit **20** in coordination with the perpendicularly aligned rotary motor **16**. More specifically, the position of the roller **28** may be adjusted either longitudinally or laterally. By placing the roller **28** longitudinally closer to the rotary motor **16**, the radius of curvature of the fluid conduit **20** is increased for a selected angular displacement of the slotted lever **80**. Alternately, by placing the roller **28** longitudinally further away from the rotary motor **16**, the radius of curvature of the fluid conduit **20** is decreased for a particular angular displacement of the drive disc **46**. Further, in resisting the lateral displacement of the fluid conduit **20** during an applied bending stress by the rotary motor **16**, the roller **28** applies a later "push" force against the fluid conduit **20**. This lateral push force is useful in testing the durability and fatigue characteristics of a stent-graft to such lateral forces. Further, the roller **28** may be reciprocatingly driven to apply lateral push forces independently of the rotary motor **16**.

[0036] In light of the above description of the various components of the vascular prosthesis tester **10**, the operation of the tester **10** will now be discussed. The rotary motors **12** and **16**, the linear motor **52**, the roller **28**, and the diaphragm pump **18**, collectively referred to as force applicators or actuators, may induce stresses individually or in various combinations. As discussed above, the force applicators may apply forces in an oscillating fashion to simulate normal physiologic movements, such as cyclic bending to simulate walking, or in a variable manner to simulate gradual changes, such as would be caused by changes in aneurysm morphology. The force applicators used to apply these forces may be electrical, mechanical, pneumatic, or hydraulic, or of other constructs known in the art.

[0037] In reference to the diaphragm pump **18**, the internal pressure is preferably cycled at a selected, relatively high frequency so that several years of heartbeats can be simulated in a short time frame. At the same time, the other forces mentioned above may be applied to the stent-graft to simulate physiological stresses induced upon the stent-graft by physiologic movements of a human, such as walking. When it is desired to simulate normal physiologic movement, the other forces will be applied cyclically at a frequency that is scaled in proportion to the frequency of the cyclic pressure gradient to correspond to the movement being modeled. For example, the frequency of the application of stresses simulating walking would be calculated by the formula:

$$\text{test frequency} = \text{pressure frequency} \frac{\text{normal step frequency}}{\text{normal heart rate}}$$

[0038] For example, if one wishes to model a human walking at the rate of 100 steps per minute, at a heart rate of 150 beats per minute, with the diaphragm pump operating at a pressure frequency of 2000 beats per minute, the actuators simulating the physiological forces of walking would be operated at a frequency of 1333 stresses or cycles per minute. As should be apparent to one skilled in the art, operating under the above parameters, the test device **10** would simulate the stresses induced by a human walking for 13.3 minutes in one minute.

[0039] The vascular prosthesis tester **10** includes a well known microprocessor based data acquisition and control system (not shown). Such a system, such as that disclosed in U.S. Pat. No. 5,670,708, issued to Vilendrer, the disclosure of which is hereby expressly incorporated by reference, will allow a user to selectively control and record the stresses induced upon the stent-graft. The system includes a series of transducers. In one embodiment, the data acquisition and control system includes well known pressure, linear displacement, radial displacement and temperature transducers, to facilitate the recordation and production of feedback control signals, and angular displacement transducers to measure the angular displacement of the rotary motors.

[0040] The transducers measure the forces applied to the fluid conduit **20**. The data acquisition and control system

records the data received from the transducers and processes the data to provide actuator control commands in response to the data as is well known in the art. The data acquisition and control system further includes a heating element that is controlled via a closed loop PID control system. The PID control system includes a conventional temperature transducer and heating element coupled to both a microprocessor-based temperature controller and the fluid conduit to maintain the fluid at a selected temperature, such as 37° C.

[0041] Referring now to FIGS. **2-4**, three alternate embodiments of vascular prosthesis testers **100**, **200**, and **300**, all formed in accordance with the present invention, will now be described in greater detail. The vascular prosthesis testers **100**, **200**, and **300** are substantially similar in materials and operation as the embodiment described above in **FIG. 1**, with the exception that the vascular prosthesis testers depicted in FIGS. **2-4** have been modified to test bifurcated vascular prosthesis, such as a bifurcated stent-graft **122**, **222**, and **322**. The bifurcated stent-graft is comprised of a main channel that divides into a first and a second branch. The bifurcated stent-graft is placed within a similarly shaped fluid conduit **120**, **220**, and **320** having a main channel **158**, **258**, and **358** and a first branch **160**, **260**, and **360** and a second branch **162**, **262**, and **362**, to form branched test members **119**, **219**, and **319**.

[0042] Inasmuch as there are now three portions of the fluid conduit **120**, **220**, and **320** for attaching force actuators thereupon, it should be apparent to one skilled in the art that the possible testing configurations is significantly increased. Although some exemplary examples of possible configurations will be described following, it should be apparent to one skilled in the art the disclosed embodiments are exemplary in nature, and other testing configurations are suitable for use and within the scope of the present invention.

[0043] Referring to **FIG. 2**, in a first alternate embodiment, the first branch **160** of the fluid conduit **120** is coupled to a fixed conduit adapter **164**. The fixed conduit adapter **164** serves to rigidly suspend an end of the fluid conduit **120** during testing. The fixed conduit adapter **164** is comprised of a generally horizontal oriented cylinder **166** attached to a telescoping extension arm **168**. The extension arm **168** is coupled to a base **170** for rigidly supporting the extension arm **168** as it supports the cylinder **166** in a stable and stationary manner a selected distance above a surface (not shown). The extension arm **168** is adjustable in length to allow the height of the cylinder **166** to be selectively adjusted. Alternately, the cylinder **166** may be reciprocatingly driven to apply lateral push forces and/or bending forces upon the fluid conduit **120**.

[0044] The cylinder **166** has an outer diameter selected to sealing engage the inner surface of the first branch **160** of the fluid conduit **120**. The sealing engagement of the cylinder **166** with the first branch **160** may be enhanced with a suitable device, such as a sealing compound, O-ring disposed in an annular channel on the fixed conduit adapter, or a well known mechanical fastener. A longitudinal fluid passageway **172** passes through the cylinder **166** of the fixed conduit adapter **164**. The passageway **172** allows the passage of a pressurized fluid generated in a diaphragm pump **118** to pass through the cylinder **166** and into the fluid conduit **120**.

[0045] Once installed, a first end of the cylinder **166** is coupled to the first branch **160** of the fluid conduit **120**. A second end of the cylinder **166** is coupled to a tube **176** coupled to the diaphragm pump **118**. Thus, a fluid pulse generated in the diaphragm pump **118** passes through the tube **176** and through the passageway **172** in the cylinder **166**, and into the first branch **160** of the fluid conduit **120**, thereby exhibiting radial and fluid shear stresses upon the fluid conduit **120** and the stent-graft **122** contained therein. Likewise, a fluid pulse generated in the diaphragm pump **118** may simultaneously pass through a second tube **178** through a longitudinal fluid passageway **173** in a fitting **126** and into the second branch **162** of the fluid conduit **120**.

[0046] Although the embodiment depicted in **FIG. 2** is described as having passageways **172** and **173** in both the cylinder **166** of the fixed conduit adapter **164** and the fitting **126**, it should be apparent to one skilled in the art that the passageways **172** and **173** may be selectively configured so that either, neither, or one of the passageways **172** allow the passage of a fluid therethrough, depending on the needs of the user. If both passageways **172** are eliminated or blocked, then diaphragm pump **118** and the diaphragm pump's associated tubes **176** and **178** may also be eliminated.

[0047] The operation and physical make-up of the remaining components of the vascular prosthesis tester **100** are substantially similar to that described above for the vascular prosthesis tester **10** of **FIG. 1**, and therefore will not be described in further detail herein.

[0048] Referring to **FIG. 3, a** second alternate embodiment of a vascular prosthesis tester **200** formed in accordance with the present invention will now be described in greater detail. The vascular prosthesis tester **200** is substantially similar in materials and operation as the embodiment described above and depicted in **FIG. 2**, with the exception that vascular prosthesis tester **200** has been modified to simultaneously apply a bend stress to both a first and a second branch **260** and **262** of a fluid conduit **220** containing a bifurcated stent-graft **222**.

[0049] To aid in applying simultaneous bend stresses to both a first and a second branch **260** and **262** of the fluid conduit **220**, a bifurcated conduit adapter **281** is used. The bifurcated conduit adapter **281** is comprised of two cylinders **266** both rigidly (or alternately pivotally) coupled to a shaft **282** oriented generally perpendicular to the length of the cylinders **266**. A driven portion **284** of the shaft **282** extends outward and generally perpendicular to the length of the cylinders **266**. The driven portion **284** interfaces with a slotted lever **280** coupled to a distal end of a drive shaft **283** of a rotary bend motor **216**, in an identical manner as to that described for the embodiment depicted in **FIG. 1**.

[0050] Referring to **FIG. 4, a** third alternate embodiment of a vascular prosthesis tester **300** formed in accordance with the present invention will now be described in greater detail. The vascular prosthesis tester **300** is substantially similar in materials and operation as the embodiment described above and depicted in **FIG. 2**, with the exception that the vascular prosthesis tester **300** has been modified to apply a bending stress to a main channel **358** of a fluid conduit **320** while applying a torque stress to a first branch **360** of the fluid conduit **320** containing a bifurcated stent-graft **322**.

[0051] Referring to **FIG. 5, a** fourth alternate embodiment of a vascular prosthesis tester **400** formed in accordance

with the present invention will now be described in greater detail. The vascular prosthesis tester **400** is similar in materials and operation as the embodiment described above and depicted in **FIG. 1**, with the exception that a test member **419** of the vascular prosthesis tester **400** does include a fluid conduit. More specifically, a first end of the vascular prosthesis, such as a stent-graft **422**, directly and sealingly engages a drive shaft **434** of a rotary motor **412**. Likewise, a second end of the stent-graft **422** directly and sealing engages a fitting **426**. Configured as such, the need for a fluid conduit to house the stent-graft **422** is eliminated. As should be apparent to one skilled in the art, the concept of having a test member wherein the fluid conduit has been eliminated, and attaching the stent-graft **422** directly to the force actuators, is not limited to the testing configuration depicted in **FIG. 5**, but has wide application, and is suitable for any testing configuration, including but not limited to those depicted in FIGS. **1-4**.

[**0052**] Referring to **FIG. 6, a** fifth alternate embodiment of a vascular prosthesis tester **500** formed in accordance with the present invention will now be described in greater detail. The vascular prosthesis tester **500** is substantially similar in materials and operation as the embodiment described above and depicted in **FIG. 1**, with the exception that a test member **519** is comprised of a fluid conduit **520** inserted within the tubular core of a vascular prosthesis, such as a stent-graft **522**, such that the stent-graft **522** now envelopes the fluid conduit **520**. More specifically, a first end of the fluid conduit **520** directly and sealingly engages a drive shaft **534** of a rotary motor **512**. A second end of the fluid conduit **520** directly and sealing engages a fitting **526**. Inasmuch as the stent-graft **522** engages the outer surface of the fluid conduit **520**, any bending stresses, torque stresses, linear compressive or tensile stresses, or hoop stresses exhibited upon the fluid conduit are also exhibited upon the stent-graft **522**. As should be apparent to one skilled in the art, the concept of forming a test member by placing the stent-graft upon the exterior of the fluid conduit is not limited to the testing configuration depicted in **FIG. 6**, but has wide application, and is suitable for any testing configuration, including but not limited to those depicted in FIGS. **1-4**.

[**0053**] While the preferred embodiment of the invention has been illustrated and described, it will be appreciated that various changes can be made therein without departing from the spirit and scope of the invention.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A vascular prosthesis tester for inducing mechanical stresses upon a test member, the test member comprising a channel extending along a longitudinal axis and a vascular prosthesis, the vascular prosthesis tester comprising:

(a) a pump adaptable to couple in fluid communication with the test member to pressurize a fluid disposed within the channel to induce a radial strain upon the vascular prosthesis; and

(b) a bend applicator operable to engage the test member to induce a bending stress upon the vascular prosthesis by bending the test member substantially along the longitudinal axis.

2. The vascular prosthesis tester of claim 1, wherein the pump is operable to induce an oscillating fluid pressure upon the fluid disposed within the channel.

3. The vascular prosthesis tester of claim 1, wherein the bend applicator is operable to induce an oscillating bending stress upon the vascular prosthesis.

4. The vascular prosthesis tester of claim 1, further comprising a torque applicator operable to engage the test member to induce a torque oriented substantially about the longitudinal axis upon the vascular prosthesis.

5. The vascular prosthesis tester of claim 4, wherein the torque applicator is coupled to a linear force applicator operable to induce linear movement to the torque applicator substantially parallel with the longitudinal axis to thereby apply a linear force oriented substantially parallel with the longitudinal axis upon the vascular prosthesis.

6. The vascular prosthesis tester of claim 1, further comprising a linear force applicator operable to induce a linear force oriented substantially parallel with the longitudinal axis upon the vascular prosthesis.

7. The vascular prosthesis tester of claim 1, further comprising a stop operable to engage the test member to impede perpendicular movement of the vascular prosthesis in at least one direction at a location spaced from the bend applicator.

8. The vascular prosthesis tester of claim 1, wherein the test member is comprised of a fluid conduit having a passageway extending along the longitudinal axis, wherein the passageway is operable to receive the vascular prosthesis therewithin, and wherein the fluid conduit is adaptable to couple in fluid communication with the pump and engage the bend applicator.

9. The vascular prosthesis tester of claim 1, wherein the test member is comprised of a fluid conduit having a passageway extending along the longitudinal axis wherein the fluid conduit is operable to be at least partially disposed within an inner channel of the vascular prosthesis, and wherein the fluid conduit is adaptable to couple in fluid communication with the pump.

10. The vascular prosthesis tester of claim 1, wherein the test member is comprised of a branched fluid conduit having a branched passageway extending through the branched fluid conduit, wherein the branched passageway is operable to receive a branched vascular prosthesis therewithin, and wherein the branched fluid conduit is adaptable to couple in fluid communication with the pump and engage the bend applicator.

11. The vascular prosthesis tester of claim 1, wherein the pump and the bend applicator are adaptable to couple to a first end of the test member.

12. The vascular prosthesis tester of claim 11, further comprising a torque applicator operable to couple to a second end of the test member to induce a torque oriented substantially about the longitudinal axis upon the vascular prosthesis.

13. A vascular prosthesis tester for inducing mechanical stresses upon a test member, the test member comprising a channel extending along a longitudinal axis and a vascular prosthesis, the vascular prosthesis tester comprising:

(a) a pump adaptable to couple in fluid communication with the test member to inject a pressurized fluid within the channel to induce a radial strain upon the vascular prosthesis; and

(b) a torque applicator operable to engage the test member to induce a torque oriented substantially about the longitudinal axis upon the vascular prosthesis.

14. The vascular prosthesis tester of claim 13, wherein the pump is operable to induce an oscillating fluid pressure within the channel.

15. The vascular prosthesis tester of claim 13, wherein the torque applicator is operable to induce an oscillating torque stress upon the vascular prosthesis.

16. The vascular prosthesis tester of claim 13, wherein the torque applicator is operable to engage a first end of the test member and the pump is operable to couple in fluid communication with a second end of the test member.

17. The vascular prosthesis tester of claim 13, wherein the torque applicator is coupled to a linear force applicator operable to induce linear movement to the torque applicator substantially parallel with the longitudinal axis to thereby apply a linear force oriented substantially parallel with the longitudinal axis upon the vascular prosthesis.

18. The vascular prosthesis tester of claim 13, further comprising a bend applicator operable to engage the test member to induce a bending stress substantially along the longitudinal axis by bending the vascular prosthesis.

19. The vascular prosthesis tester of claim 13, further comprising a linear force applicator operable to induce a linear force oriented substantially parallel with the longitudinal axis upon the vascular prosthesis.

20. The vascular prosthesis tester of claim 13, further comprising a stop operable to engage the test member to impede perpendicular movement of the vascular prosthesis in at least one direction.

21. The vascular prosthesis tester of claim 13, wherein the test member is comprised of a fluid conduit having a passageway extending along the longitudinal axis, wherein the passageway is operable to receive the vascular prosthesis therewithin, and wherein the fluid conduit is adaptable to couple in fluid communication with the pump and engage the torque applicator.

22. The vascular prosthesis tester of claim 13, wherein the test member is comprised of a fluid conduit having a passageway extending along the longitudinal axis, wherein the fluid conduit is operable to be at least partially disposed within an inner channel of the vascular prosthesis, and wherein the fluid conduit is adaptable to couple in fluid communication with the pump and engage the torque applicator.

23. The vascular prosthesis tester of claim 13, wherein the test member is comprised of a branched fluid conduit having a branched passageway extending through the branched fluid conduit, wherein the branched passageway is operable to receive a branched vascular prosthesis therewithin, and wherein, the branched fluid conduit is adaptable to couple in fluid communication with the pump and engage the torque applicator.

24. A vascular prosthesis tester for inducing mechanical stresses upon a test member having a channel extending along a longitudinal axis and a vascular prosthesis, the vascular prosthesis tester comprising:

(a) a pump adaptable to couple in fluid communication with the test member to inject a pressurized fluid within the channel to induce a radial strain upon the vascular prosthesis; and

(b) a linear force applicator operable to induce linear forces oriented substantially parallel with the longitudinal axis upon the vascular prosthesis.

25. The vascular prosthesis tester of claim 24, wherein the pump is operable to induce an oscillating fluid pressure within the channel.

26. The vascular prosthesis tester of claim 24, wherein the linear force applicator is operable to induce an oscillating linear force upon the vascular prosthesis.

27. The vascular prosthesis tester of claim 24, wherein the pump is adaptable to couple to a first end of the test member and the linear force applicator is operable to induce the linear forces upon a second end.

28. The vascular prosthesis tester of claim 24, further comprising a torque applicator coupled to the linear force applicator, wherein the linear force applicator is operable to induce linear movement to the torque applicator to thereby apply the linear forces.

29. The vascular prosthesis tester of claim 24, further comprising a bend applicator operable to engage the test member to induce a bending stress upon the vascular prosthesis by bending the test member substantially along the longitudinal axis.

30. The vascular prosthesis tester of claim 24, further comprising a torque applicator operable to engage the test member to induce a torque oriented substantially about the longitudinal axis upon the vascular prosthesis.

31. The vascular prosthesis tester of claim 24, further comprising a stop operable to engage the test member to impede perpendicular movement of the test member in at least one direction.

32. The vascular prosthesis tester of claim 24, wherein the test member is comprised of a fluid conduit having a passageway extending along the longitudinal axis, wherein the passageway is operable to receive the vascular prosthesis therewithin, and wherein the fluid conduit is adaptable to couple in fluid communication with the pump and be engaged by the linear forces induced by the linear applicator.

33. The vascular prosthesis tester of claim 24, wherein the test member is comprised of a fluid conduit having a passageway extending along the longitudinal axis, wherein the fluid conduit is operable to be at least partially disposed within an inner channel of the vascular prosthesis, and wherein the fluid conduit is adaptable to couple in fluid communication with the pump and to be engaged by the linear forces induced by the linear force applicator.

34. The vascular prosthesis tester of claim 24, wherein the test member is comprised of a branched fluid conduit having a branched passageway extending through the branched fluid conduit, wherein the branched passageway is operable to receive the vascular prosthesis therewithin, and wherein the branched fluid conduit is coupled in fluid communication with the pump and engaged by the linear forces induced by the linear force applicator.

35. A vascular prosthesis tester for inducing mechanical stresses upon a test member, the test member comprising a channel extending along a longitudinal axis and a vascular prosthesis, the vascular prosthesis tester comprising:

(a) a pump adaptable to couple in fluid communications with the test member to pressurize a fluid disposed within the channel to induce a radial stress upon the vascular prosthesis;

(b) a bend applicator operable to engage the test member to induce a bending stress upon the vascular prosthesis by bending the test member substantially along the longitudinal axis;

(c) a torque applicator operable to engage the test member to induce a torque oriented substantially about the longitudinal axis upon the vascular prosthesis; and

(d) a linear force applicator operable to induce a linear force oriented substantially parallel with the longitudinal axis upon the vascular prosthesis.

36. The vascular prosthesis tester of claim 35, wherein the pump is further comprised of a diaphragm adaptable to have the fluid disposed on a first side of the diaphragm, and a driver coupled to the diaphragm for driving the diaphragm in a reciprocating manner, thereby permitting the selective pressurization of the fluid.

37. The vascular prosthesis tester of claim 35, wherein the bend applicator is comprised of a rotary motor having a driven member that rotates on an axis oriented substantially perpendicular to the longitudinal axis, wherein the driven member is operable to apply a bending stress upon the vascular prosthesis by bending the vascular prosthesis substantially along the longitudinal axis.

38. The vascular prosthesis tester of claim 35, wherein the torque applicator is comprised of a rotary motor having a driven member that rotates on an axis oriented substantially parallel to the longitudinal axis, wherein the driven member is operable to couple to the test member to apply a torque upon the vascular prosthesis.

39. The vascular prosthesis tester of claim 35, wherein the linear force applicator is comprised of a linear actuator operable to apply tensile and compressive linear forces aligned substantially parallel with the longitudinal axis upon the vascular prosthesis.

40. The vascular prosthesis tester of claim 35, wherein the pump is operable to induce an oscillating fluid pressure within the channel.

41. The vascular prosthesis tester of claim 35, wherein the bend applicator is operable to induce an oscillating bending stress upon the vascular prosthesis.

42. The vascular prosthesis tester of claim 35, wherein the torque applicator is operable to induce an oscillating torque upon the vascular prosthesis.

43. The vascular prosthesis tester of claim 35, wherein the linear force applicator is operable to induce an oscillating linear force upon the vascular prosthesis.

44. The vascular prosthesis tester of claim 35, wherein the pump is adaptable to couple in fluid communication to a first end of the test member and the torque applicator is operable to couple to a second end of the test member.

45. The vascular prosthesis tester of claim 35, wherein the torque applicator is coupled to the linear force applicator, wherein the linear force applicator is operable to induce linear movement of the torque applicator to thereby apply the linear force.

46. The vascular prosthesis tester of claim 35, wherein the pump and the bend applicator are operable to couple to a first end of the test member and the torque applicator is operable to engage a second end of the test member.

47. The vascular prosthesis tester of claim 35, wherein at least one from the group consisting of the pump, bend applicator, torque applicator, and linear force applicator are operable to apply a variable stress upon the vascular prosthesis and one from the group consisting of the pump, bend applicator, torque applicator, and linear force applicator are operable to apply an oscillating stress upon the vascular prosthesis.

48. The vascular prosthesis tester of claim 35, further comprising a stop operable to engage the test member to impede perpendicular movement of the vascular prosthesis in at least one direction.

49. The vascular prosthesis tester of claim 35, wherein the test member is comprised of a fluid conduit having a passageway extending along a longitudinal axis, wherein the passageway is operable to receive the vascular prosthesis therewithin, and wherein the fluid conduit is adaptable to couple in fluid communication with the pump.

50. The vascular prosthesis tester of claim 35, wherein the test member is comprised of a fluid conduit having a passageway extending along a longitudinal axis, wherein the fluid conduit is operable to be at least partially disposed within an inner channel of the vascular prosthesis, and wherein the fluid conduit is adaptable to couple in fluid communication with the pump.

51. The vascular prosthesis tester of claim 35, wherein the test member is comprised of a branched fluid conduit having a branched passageway extending through the branched fluid conduit, wherein the branched passageway is operable to receive a branched vascular prosthesis therewithin, wherein the fluid conduit is adaptable to couple in fluid communication with the pump.

52. A method of fatigue testing a test member comprising an inner channel oriented along a longitudinal axis and a vascular prosthesis, the method comprising:

(a) injecting a pressurized fluid within the inner channel to induce a radial stress upon the vascular prosthesis; and

(b) inducing a bending stress oriented substantially along the longitudinal axis upon the vascular prosthesis.

53. The method of claim 52, wherein the fluid is injected by a pump coupled in fluid communication to a first end of the test member.

54. The method of claim 52, wherein the bending stress is applied by a bend applicator coupled to a first end of the test member.

55. The method of claim 52, further comprising inducing a torque oriented substantially about the longitudinal axis upon the vascular prosthesis.

56. The method of claim 52, wherein the torque is induced by a torque applicator comprised of a rotary motor adaptable to couple to a second end of the test member.

57. The method of claim 52, further comprising inducing a linear force oriented substantially along the longitudinal axis upon the vascular prosthesis.

58. The method of claim 52, wherein the linear force is applied by a linear force actuator operable to move an adapter coupled to the test member along the longitudinal axis to induce a linear stress in the vascular prosthesis.

59. A method of fatigue testing a test member comprising an inner channel oriented along a longitudinal axis and a vascular prosthesis, the method comprising:

(a) injecting a pressurized fluid within the inner channel to induce a radial stress upon the vascular prosthesis; and

(b) inducing a torque upon the vascular prosthesis oriented substantially about the longitudinal axis.

60. The method of claim 59, wherein the fluid is injected by a pump coupled in fluid communication to a first end of the test member.

61. The method of claim 60, wherein the torque is applied by a torque applicator coupled to a second end of the test member.

62. The method of claim 59, further comprising inducing a bending stress oriented substantially along the longitudinal axis upon the vascular prosthesis.

63. The method of claim 59, wherein the bending stress is induced by a bend applicator comprised of a rotary motor adaptable to couple to a first end of the test member.

64. The method of claim 59, further comprising inducing a linear force oriented substantially along the longitudinal axis upon the vascular prosthesis.

65. The method of claim 59, wherein the linear force is applied by a linear force actuator operable to move an adapter coupled to the test member along the longitudinal axis to induce a linear stress in the vascular prosthesis.

66. A method of fatigue testing a test member comprising an inner channel oriented along a longitudinal axis and a vascular prosthesis, the method comprising:

(a) injecting a pressurized fluid within the inner channel to induce a radial stress upon the vascular prosthesis; and

(b) applying a linear force upon the vascular prosthesis oriented substantially along the longitudinal axis.

67. The method of claim 66, wherein the linear force is applied by a linear force actuator operable to move an adapter coupled to the test member along the longitudinal axis to induce a linear stress in the vascular prosthesis.

68. The method of claim 66, further comprising inducing a bending stress oriented substantially along the longitudinal axis upon the vascular prosthesis.

69. The method of claim 66, wherein the bending stress is induced by a bend applicator comprised of a rotary motor adaptable to couple to a first end of the test member.

70. The method of claim 66, further comprising inducing a torque oriented substantially about the longitudinal axis upon the vascular prosthesis.

71. The method of claim 66, wherein the torque is applied by a torque applicator coupled to a second end of the test member.

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